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**Patent and Trademark Office**  
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Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fisher's Lane, Room 11-44  
Rockville, MD 20857

Dear Mr. Wilson:

The enclosed application for extension of the patent term of U.S. Patent No. 4,338,317 issued on July 6, 1982, was filed on January 20, 1995, under 35 USC § 156.

Your assistance is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156(g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A).

Our review of the application to date indicates that the subject matter would be eligible for extension of the patent term under 35 USC § 156.

Gerald A. Dost  
Gerald A. Dost  
Special Program Examiner  
Office of Special Programs  
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for Patent Policy and Projects

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cc: Richard P. Ryan  
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